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| 10/016,243      | 12/10/2001  | Dinesh O. Shah       | 5853-184US          | 4551             |

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EXAMINER

METZMAIER, DANIEL S

ART UNIT

PAPER NUMBER

1712

9

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/016,243

Applicant(s)

PARMAR ET AL.

Examiner

Daniel S. Metzmaier

Art Unit

1712

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,10-15,19 and 20 is/are rejected.
- 7) ☒ Claim(s) 2,6 and 16-18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

### DETAILED ACTION

Claims 1-6 and 10-20 are pending. This action is responsive to the amendment filed March 10, 2003, Paper No. 6. Claims 7-9 were canceled by said amendment.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3 and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3, it is unclear whether said oil varies from 0.001 to 5 wt/wt% of the oil phase or said oil varies from 0.001 to 5 wt/wt% of the microemulsion.

Claims 12-14 are indefinite because use is not a proper method step. While said claims have been amended to include the step of "providing", it is unclear how applicants are "using" said microemulsion, eg., as a topical coating, in vivo, as an adjuvant, as a active agent, etcetera.

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3-5, 15 and 19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Goddard et al, 4,704,220. Goddard et al (Table III) discloses a corn oil microemulsion employing 1 gram of corn oil, 1 gram of Tergitol NP4 (understood to be defined as in example 1A, column 11, lines 21-23), ethoxylated nonylphenol having an average of 4 ethoxy units, and 4 grams Tergitol 25L7, an ethoxylated linear alcohol having 12 to 15 carbon atoms and an average of 7 ethoxy units. Said combinations are combined with base fluid A from example 1. Base fluid A contains salts and ethylene glycol. The Goddard et al reference does not include a ionic cosurfactant in the compositions. The ethylene glycol

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in the Goddard et al composition is a glycol and not a primary short chain (C1 to C6) alcohol excluded from the instant claims.

In example 5, Goddard et al discloses the antifreeze is diluted 50:50 with tap water. The microemulsions claimed (dilutable) read on the corn oil emulsion of the Goddard et al reference. The aqueous microemulsion composition would have been inherent to the Goddard et al reference.

To the extent the Goddard et al reference differs from the claims in the actual dilution of the corn oil emulsion and the characterization thereof as a microemulsion, the Goddard et al reference (column 13, lines 60-68) teaches various oils may be employed including vegetable oil. Goddard et al (example 5) further teaches the compositions have a cloud point, which clearly indicates the existence of an optically clear solution.

7. Claims 10-11 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goddard et al, 4,704,220. Goddard et al discloses microemulsions as set forth above in the preceding rejection.

Goddard et al differs from the claims in the exemplified concentration of the oil and/or the surfactant.

Goddard et al (column 9, lines 20-35) teaches the emulsifier can be employed at 0.1 to 100 times the amount of oil employed. Goddard et al (column 4, lines 41-53) teaches the oil is employed at about 0.001 to about 5 wt% of the microemulsion.

It would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to vary the concentrations of the Goddard et al reference within

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those taught as an obvious variation of the prior art disclosed compositions having utility as an antifreeze.

***Allowable Subject Matter***

8. Claims 2, 6, 16, 17 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not disclose microemulsion compositions employing nonionic alkyl phenol ethoxylated surfactants as a single surfactant in the absence of a primary short chain (C1 to C6) alcohol and in the absence of an ionic cosurfactant.

The prior art of record does not disclose microemulsion compositions employing nonionic alkyl phenol ethoxylated surfactants to make neem oil microemulsion in the absence of a primary short chain (C1 to C6) alcohol and in the absence of an ionic cosurfactant.

***Response to Arguments***

10. Applicant's arguments with respect to claims 1-6 and 10-20 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

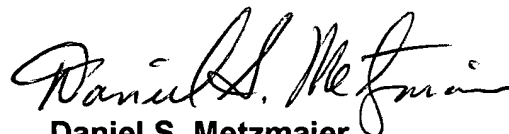
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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel S. Metzmaier whose telephone number is (703) 308-0451. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Dawson can be reached on (703) 308-2340. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



**Daniel S. Metzmaier**  
**Primary Examiner**  
**Art Unit 1712**

DSM  
June 30, 2003